Frequently Asked Questions

Logistics and Supply Chain Management of HIV Tests

What is an HIV test?

When used correctly, HIV tests can determine if HIV is present in a person's blood. HIV tests do not test for the virus itself. Instead, they detect either antibodies to the virus or HIV antigens (specific viral proteins). Some newer tests can detect both. If antibodies or antigens are detected consistently, the person has an "HIV positive" result, indicating the presence of HIV.

Why would an HIV test be used?

- **Blood safety:** To screen blood units and blood donors for transfusion safety.
- **Clinical diagnosis:** To determine if a patient has HIV.
- **Voluntary counseling and testing (VCT):** To facilitate behavior change.
- **Sentinel surveillance:** To monitor the epidemic.
- **Preventing mother-to-child transmission (PMTCT):** To determine if services are needed to prevent transmission of the virus.
- **Other:** To use in special studies or for training health care providers.

If HIV is detected early enough, clients have more opportunities to take control of their health and increase their chances for leading a productive and satisfying life.

What types of HIV tests are available?

- Simple / rapid assay (rapid test devices or RTDs) are easy to perform, require little or no additional equipment, and can process a small number of samples.
- ELISA (enzyme-linked immunosorbent assay) tests require sophisticated equipment and skilled technicians, and can screen a large number of samples at one time.
- Western blot tests require specialized skills and equipment and are very expensive.

Only the first two types of tests—RTDs and ELISAs—are widely used in resource-constrained settings. Studies have shown that combinations of simple / rapid assays or ELISAs can provide results that are as reliable as the Western blot but at a much lower cost.

The technology for HIV tests is evolving rapidly. In the next few years, many new and improved tests will replace current ones.

How do you select appropriate HIV tests?

Most programs use different combinations of tests and different testing algorithms for each reason for testing. Selection of HIV tests should be based on the following criteria:

- An evaluation of the sensitivity and specificity of the test in the country setting.
- Reason for testing (blood safety, VCT, sentinel surveillance, etc.).
- Estimated HIV prevalence in the population.
- How quickly the test result is needed.
- Size of the facility and how many tests are likely to be conducted simultaneously.
- Tests that are registered and approved for use in the country.
- Budget available for the purchase of HIV tests.

What is the shelf life of HIV tests?

The shelf life of HIV tests tends to be short, from 5 to 15 months, with most between 9 and 12 months. Due to the relatively short shelf life, it is crucial to standardize and closely manage the procurement process; purchase a select number of brands; and monitor storage, distribution, and use before the tests expire.

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How much do HIV tests cost?

Costs for the tests vary considerably depending on the type of test; brand; quantity being procured; and negotiations between the supplier, distributor, and purchaser.

How should HIV tests be distributed?

Most HIV tests need special handling by trained personnel, and they require specific equipment and consumables throughout the supply chain. Due to the short shelf life, these elements must be in place to minimize expiration and wastage.

When should a country buy HIV tests?

Before HIV tests are procured, a country/program should have a national policy for HIV testing in place, and be able to meet basic conditions at each site where tests will be used. Ideally, the national policy will outline the country's comprehensive strategy to respond to HIV/AIDS, including details about HIV testing.

What important issues should be included in a country's national policy?

Each country is unique, and should address its national interests differently. However, any national framework on HIV testing should include the following elements:

- Blood safety.
- Sentinel surveillance.
- Individual diagnosis.
- VCT.
- PMTCT.
- Standardized HIV testing algorithms for each reason for testing.
- Skills-based training and follow-up for health personnel.
- Universal safety precautions and procedures for safe disposal of used tests.
- National guidelines to ensure patient confidentiality and reduce discrimination.
- Record keeping for health and logistics management information systems.

HIV Tests

Test	Site of Use	Advantages	Limitations	Cost
Simple/rapid assay **(Rapid test device)**	Small labs, VCT sites, PMTCT sites, STD and TB clinics, and emergency care centers.	• Easy to use and interpret test results. • Results within 10–30 minutes. • No minimum volume of tests required. • Minimal equipment required. • Does not require highly skilled staff. • Many newer tests can be stored at room temperature. • When used in combination, results as reliable as ELISAs. • Can be used on various types of specimens, including whole blood. • Oral fluid tests have been developed recently, are non-invasive, and do not require sharps.	• Small-scale testing. • Considerable variation in sensitivity. However, this often depends on type of specimen (i.e., whole blood, serum, oral fluid). • Cold chain is sometimes required. • May cost more per individual test.	Relatively expensive.
ELISA	Large hospitals, blood banks, or reference labs.	• Highly sensitive. • Batch testing. • Can be automated. • Easier to conduct quality assurance testing, because tests are performed in fewer laboratories.	• Requires more time to obtain results (1–3 hours). • Need sophisticated equipment and equipment maintenance. • Cold chain always required. • Need minimum volume of tests for maximum efficiency. • Requires skilled technicians.	Relatively more expensive than rapid test device, but cost-effective for large batches. Can be expensive if only used for small batches.
Western blot	Large teaching hospitals, reference laboratories, and National Reference Laboratory.	• The "Gold Standard." • Detects all antibodies present.	• Requires skilled and experienced personnel. • Non-routine test (small batches only, usually < 10) used for research and clarifying indeterminate results.	Very expensive.